

In the United States Court of Federal Claims

No. 14-560V

(Originally filed under seal: October 13, 2020)

(Re-filed: November 12, 2020)¹

JEAN YATES Individually and as
representative of the late ROBERT YATES,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

National Childhood
Vaccine Injury Act, 42
U.S.C. §§300aa-1 to -34
(2012); Motion for
review; Meningococcal
conjugate (“Menactra”)
vaccine; Off-table claim;
Causation.

Patricia Finn, Piermont, NY, for petitioner.

Voris E. Johnson, Senior Trial Attorney in the Torts Branch of the Civil Division, Department of Justice, Washington, DC, with whom were *Joseph H. Hunt*, Assistant Attorney General, *trC. Salvatore D’Alessio*, Acting Director, *Catharine E. Reeves*, Deputy Director, and *Alexis B. Babcock*, Assistant Director, for respondent.

OPINION

BRUGGINK, *Judge.*

This is a case brought under the National Childhood Vaccine Injury Act for compensation for injuries allegedly sustained after Robert Joseph

¹ This opinion was held for fourteen days during which the parties were permitted to propose to chambers any appropriate redactions. The parties did not propose any redactions and thus we re-issue the decision without redactions. Rules of the United States Court of Federal Claims, App. B, Rule 18(b) (“Vaccine Rules”).

Yates received the meningococcal conjugate (“Menactra”) vaccine on July 27, 2012. Robert’s mother, Jean Yates (“petitioner”) filed a petition on behalf of her deceased son on June 30, 2014, alleging that the administration of the Menactra vaccine by Mount Kisco Medical Group caused Robert’s death.

Pending is petitioner’s motion for review of the Special Master’s decision of April 16, 2020, denying compensation. *Yates v. Sec’y of Health & Human Servs.*, No. 14-560V, 2020 WL 2313691 (Fed. Cl. Spec. Mstr. Apr. 16, 2020). The motion is fully briefed, and the court finds that oral argument is unnecessary. Because the Special Master was not arbitrary or capricious and did not abuse her discretion in determining that petitioner had not demonstrated that the Menactra vaccine caused her son’s death, we deny the motion for review.

BACKGROUND

I. Factual History

The factual history of petitioner’s claim is not in dispute.² And although we summarize the facts and procedural history here, we adopt in full the excellent presentation by the Special Master in this difficult and complex case. Robert Joseph Yates was born on January 9, 1994. Pet.’s Ex. 1 at 9 (ECF No. 6-1) (Medical Records of Robert Yates). Robert had a history of autism and epilepsy but was otherwise healthy. *Id.* at 15. Robert attended a special needs program, and liked computers, trains, and magazines. *Id.* In 2011, Robert was treated for seizures, a fever, hematuria,³ an upper respiratory infection, a contusion on his right foot, and possible strep throat. *Id.* at 9-32. On July 20, 2011, during Robert’s 17-year-old

² Petitioner adopted the Special Master’s factual record set forth in the Special Master’s decision, and concurs it is consistent with the contemporaneous medical records proffered, and allegations in the petition. Pet.’s Mot. for Review at 3, 5 (ECF No. 98).

³ Hematuria is blood in the urine. On September 23, 2011 Robert was examined because a few drops of blood were noticed in Robert’s urine. On physical exam, Dr. Barsh noted Robert appeared healthy, showed no signs of illness, fever, and Robert was not indicating any pain, nor did he have signs of a renal stone. Pet.’s Ex. 1 at 28.

checkup, Robert's cardiac exam revealed "regular rate and rhythm without murmur, rub or gallop." *Id.* at 25. Dr. Elliot Barsh described Robert as a "well-developed, well-nourished boy, in no acute distress," and that Robert was a "healthy 17-year old young man with autistic spectrum disorder." *Id.*

The following year, Robert was treated for a persistent cough and earache, dermatitis and seizures, a deficiency in vitamin D, and possible pneumonia. *Id.* at 34-35, 37, 39. Early in 2012, on February 22nd, Robert had a neurologic appointment with Dr. Tania-Marie Sweeney who reviewed Robert's medications. *Id.* at 41. Robert was taking 2500mg of Keppra in the morning, and 3000mg of Keppra in the afternoon to control seizures. His parents had also added another pill of Keppra to Robert's evening dose following a recent seizure. *Id.*

Mr. Yates explained to Dr. Sweeney that usually he and Ms. Yates, could avoid taking Robert to the emergency room ("ER") for seizures, but, on February 9, 2012, Robert had a seizure on the school bus, and so an ambulance was called. *Id.* at 40-41. After arriving at the emergency room, Mr. Yates recommended to the medical personnel that they give Robert clonazepam, which they did. *Id.* Robert was not given Keppra even though he was due to receive a dose. *Id.* On the way home from the ER, Robert had another seizure; so Mr. Yates gave Robert another 2mg of clonazepam and Robert seemed fine. *Id.* Robert saw his pediatrician the next day because the ER doctor said Robert may have pneumonia. *Id.* The pediatrician ruled out pneumonia after she examined Robert. *Id.* Robert's February 22, 2012 examination concluded with Dr. Sweeney reviewing Robert's medications with his parents and outlining a plan to continue his current medications, which involved Robert taking 1mg of clonazepam at night, 10 mg of Valium in the morning and evening, and vitamin D weekly. *Id.* Dr. Sweeney also indicated she did not want to increase Robert's Keppra since his dosage was already high but instead wanted to conduct follow up appointments with Robert at least every six months. *Id.*

Due to continued seizure episodes, a neurologist, Dr. Alexandra E. McBride examined Robert on May 15, 2012. *Id.* at 47. At that time, Robert's medications included Keppra, Valium, and Clonazepam. The report noted that Robert had "no medication allergies." *Id.* Records from that examination described Robert's overall health as "No headaches. No visual complaints. No gait disturbance. No cardiac, pulmonary, GI, GU, dermatologic, hematologic, endocrine complaints." *Id.*

On July 27, 2012, Dr. Barsh examined Robert again for his 18-year-old physical. Pet.'s Ex. 1 at 54. Robert's medications at that time included Valium, Keppra, Depakote, and Klonopin. *Id.* Robert weighed 213.5 pounds, measured 68 inches tall, his blood pressure was 130/80, and his pulse was 80. *Id.* Dr. Barsh noted that Robert was a healthy 18-year-old with pervasive delays and epilepsy but "doing much better on his medications at this time." *Id.* Robert's cardiac exam revealed a "regular rate and rhythm without murmur, rub or gallop." *Id.* The report also mentioned that Robert attended the special education program at Fox Lane High School, worked on the computer, had decent sleep, and regular meals. *Id.* Mr. Yates was asked to talk with Robert's school about incorporating an hour of physical activity into Robert's daily routine. *Id.*

During the exam, blood work was ordered and a sample taken. One of the panels performed was as Complete Blood Count ("CBC"), which produces total cell counts in the blood sample, such as red blood cells and white blood cells. As will become apparent later, the relevant marker examined was Robert's eosinophil count, a type of white blood cell, which came back as a "9.4 %." *Id.* at 65.

At that time, Dr. Barsh discussed the benefits, risks, and possible side effects of the Menactra vaccine with Mr. Yates. Menactra is administered to immunize recipients against invasive meningococcal disease, and the vaccine is approved for administration from 9 months through 55 years of age. Pet.'s Ex. 26 at 1 (Vaccine manufacturer's package insert). Dr. Barsh provided Mr. Yates with a CDC vaccine information sheet that described meningococcal disease as a serious bacterial illness. Pet.'s Ex. 15 at 1. Robert's father gave permission to Dr. Barsh to administer the Menactra vaccine to Robert, and Dr. Barsh did so. Pet.'s Ex. 1 at 54 (medical records). The shot Robert received on July 27, 2012 was his second Menactra vaccination. Robert received his first Menactra shot on August 25, 2005. *Id.* at 67. Ms. Yates said she didn't recall Robert having any problems in 2005 after his first Menactra vaccination. Tr. at 14 (Entitlement Hearing, July 27, 2017) (ECF No. 54).

Three days later, on July 30, 2012, at about 2:30 p.m., Ms. Yates checked on Robert in his room, where he was sitting at his desk playing on the computer. Pet.'s Ex. 22 at 1. At 3:48 p.m., Ms. Yates checked on Robert again and found him "slumped down in the chair at his desk and did not appear to be breathing." His parents started cardiopulmonary resuscitation ("CPR"), and they called emergency services. *Id.*

Officer Andrew Thierstein responded to the 911 call. Pet.'s Ex. 22 at 1 (police report). Officer Thierstein followed Robert's brother to a bedroom where he observed Mr. and Ms. Yates providing CPR to their son Robert. *Id.* Robert was unresponsive, and did not appear to be breathing, but he had a faint pulse. *Id.* Officer Thierstein instructed Mr. and Ms. Yates to stop providing breaths so he could use the bag valve mask ("BMV"), but Mr. Yates refused.⁴ Pet.'s Ex. 22. Ms. Yates stated that the only way they were going to save Robert was for his father to continue giving breaths while Ms. Yates continued chest compressions. *Id.* Ms. Yates stated that "this has happened before and that they have saved their son in the past by doing what they are doing." *Id.* Mr. Yates stopped CPR a few times, and Officer Thierstein tried to use the BVM. When Officer Thierstein tried to use the BVM, Ms. Yates said that the BVM was not working and that Mr. Yates was very good at giving breaths and that he should continue CPR. *Id.* When Ms. Yates tired of giving chest compressions, Officer Thierstein took over CPR and provided CPR for about a minute until the emergency medical technicians arrived. *Id.* When Officer Thierstein spoke to Ms. Yates she explained that Robert is Autistic and suffers from seizures and that "this was not the first time something like this has happened, but it was the most serious occasion to date."⁵ *Id.*

Paramedic Walter Hughes took over care after arriving, providing compressions while Mr. Yates continued giving breaths. *Id.* Paramedic Hughes suctioned Robert two times, and attempted to use the BVM, but Ms. Yates told him that her husband could do a better job, so Paramedic Hughes stopped using the BVM, and Mr. Yates continued giving breaths. *Id.* The ambulance arrived at the Yates' residence at 3:57 p.m., and Robert was transported to the emergency room at Northern Westchester Hospital. On the way to the ER, epinephrine and sodium bicarbonate were administered to Robert, and the paramedics continued CPR.

⁴ A bag valve mask is a breathing device that fits over the patient's mouth and provides a seal. Pressurized oxygen connects to the device, and the medical provider forces oxygen into the patient's lungs by squeezing a self-inflating bag.

⁵ On December 1, 2017, petitioner filed an affidavit of Jean Yates which stated that "[t]here was never an occasion that Mr. Yates and I had to do CPR on Robert or that we called 911 or that Robert was taken to the hospital for a similar episode until July 30, 2012." ECF No. 63

Upon arrival at Northern Westchester Hospital at 4:38 p.m., Robert was diagnosed as being in cardiac arrest and was intubated. Pet.'s Ex. 2 at 7-9 (hospital records). Extensive resuscitation efforts were made, but to no avail. *Id.* At 4:57 p.m. treating physicians declared Robert dead. *Id.* at 8.

Westchester County Medical Examiner, Dr. Aleksander Milovanovic, M.D., performed an autopsy on July 31, 2020. Pet.'s Ex. 4 at 10 (Autopsy Report). Dr. Milovanovic's autopsy report detailed that Robert was found unresponsive in his home and that he had pervasive developmental disorder and generalized seizures. *Id.* at 13. The report also documented that Robert was given dissolvable clonazepam on July 30, 2012, and that he received a second Menactra vaccine on July 27, 2012. *Id.* Robert's heart showed mild hypertrophy of the left ventricle and mild dilation of the right ventricle. *Id.* Tissues samples from Robert's heart were taken from the left ventricle, septum, and anterior, lateral, and posterior walls. The neuropathology examination of those tissues revealed subepicardial myocarditis (inflammation) and the presence of lymphocytic inflammatory infiltrate with focal myocyte necrosis (cell death). *Id.* at 14. Consistent with those findings, the examiner also found "interstitial fibrosis" (lesions) with "scant lymphocytes."⁶ *Id.* Dr. Milovanovic thus determined the cause of death to be lymphocytic myocarditis. *Id.* at 10.

II. Procedural History

On June 30, 2014, petitioner timely filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§300aa-1 to -34 (2012) ("Vaccine Act"). Petitioner also filed relevant medical records. Pet.'s Ex.1-3 (ECF No. 6); Pet.'s Ex. 4-5 (ECF No. 10). Petitioner alleged Robert Yates' death was caused by the administration of the meningococcal vaccination (Menactra) administered by Mount Kisco Medical Group on July 27, 2012.

Respondent subsequently filed a report, recommending against compensation. Respondent argued that petitioner failed to provide a medical theory that connected Robert's Menactra vaccination to his cause of death, lymphocytic myocarditis, and thus failed to provide a reliable theory of causation to satisfy the causation standard of *Althen v. Sec'y of Health &*

⁶ A toxicology screen was also performed as part of the autopsy. That test revealed the presence of anti-seizure medications. No other blood tests were performed.

Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Resp't Rpt. at 5. Respondent further contended that petitioner had not established a logical sequence of cause and effect associating the Menactra vaccine with Robert's lymphocytic myocarditis "and/or death," and that petitioner had failed to establish an appropriate temporal association between Robert receiving the Menactra vaccine and the injury. *Id.*

On March 24, 2015, petitioner filed a status report detailing the medical records which indicated Robert received his first Menactra vaccine on August 25, 2005, and a second Menactra vaccine on July 27, 2012. Pet.'s Ex. 1 at 67 (ECF No. 19). Petitioner also submitted an expert report from pediatric cardiologist Dr. Anthony Chang, M.D. (ECF No. 20), and supplemental medical literature in support of Dr. Chang's expert report. ECF No. 21. On November 13, 2015, respondent filed the expert reports and curriculum vitae of pediatric cardiologist Scott B. Yeager, M.D., and pathologist Rebecca D. Folkerth, M.D. (ECF No.33). Petitioner filed Dr. Chang's reply expert report and supplemental expert report and curriculum vitae of pathologist Dr. Laurel Waters, M.D. on April 20, 2016. ECF No. 38.

The Special Master held an entitlement hearing on July 27, 2017, at which she heard testimony from the petitioner, Robert's mother, Jean Yates, and from petitioner's experts Dr. Laurel Waters and Dr. Anthony Chang. Respondent's two experts, Drs. Rebecca Folkerth and Scott Yeager, also testified at the hearing. After extensive post-trial proceedings, including the submittal of additional medical literature and briefing, the Special Master issued her decision on April 16, 2020, denying compensation.

III. The Expert Opinions

The Special Master's decision dealt largely with the parties' competing expert presentations. Petitioner's experts, Dr. Chang and Dr. Waters, offered two theories regarding Robert's death. According to Dr. Chang, Robert's death was due to acute hypersensitivity myocarditis, an inflammatory condition of the heart muscle, caused by the Menactra vaccine. Pet.'s Ex. 6 at 2 (Dr. Chang's Expert Report). Dr. Chang's reply report notes that the presence of an elevated eosinophil count (9.4%) from Robert's July 27, 2012 blood test indicated "most likely a hypersensitivity inflammatory process that is generalized." Pet.'s Ex. 11 at 4. Put another way, Robert suffered a generalized inflammatory response to the Menactra vaccine that caused heart failure, according to Dr. Chang.

It was not troubling to Dr. Chang that the autopsy examination of Robert's heart tissue did not reveal the presence of eosinophils. He submitted that the generalized inflammatory reaction in the heart "as a result of the vaccination [could] lead to an eosinophilic and/or lymphocytic myocarditis as both indicate an inflammatory process." *Id.* In sum, he relied on the presence of elevated levels of eosinophils in Robert's blood on the day of the vaccine to conclude that he had suffered a hypersensitive reaction to that vaccine. In Dr. Chang's view, that reaction caused a severe myocarditis.

In response to respondent's experts, Dr. Chang's reply report explained that, in his view, the etiology must be founded on the patient's history and other types of evidence, like a viral panel and white blood cell counts versus the "etiology of the inflammation on the cell subtypes of the inflammation."⁷ *Id.* Dr. Chang's clinical view was that Robert was "totally healthy without any cardiac or respiratory symptoms and signs upon his visit with the pediatrician and prior to his vaccination." *Id.* His sudden demise, due to heart failure three days later was the result of an "obvious hypersensitivity response to the vaccine in the form of an inflammatory process of the heart that lead to a lethal myocarditis." *Id.* Although he noted the possibility of such a response to a viral infection, he found that case to be "far less likely" in Robert's case due to the vaccine. *Id.* He noted that Dr. Waters, a pathologist, had found "no laboratory evidence (including viral panel) supportive of a viral infection." *Id.*

Petitioner's other expert, Dr. Waters provided an alternative explanation for Robert's death, also attributable to the Menactra vaccine. She opined that the vaccine caused lymphocytic myocarditis. Pet.'s Ex. 13 at 8. In contrast to Dr. Chang, she distinguished between eosinophilic (hypersensitivity) myocarditis and lymphocytic myocarditis. Dr. Waters noted from the autopsy results that, "microscopically, there was a significantly sized focus of inflammation in the heart which was primarily mononuclear with lymphocytes and macrophages." *Id.* at 4. This was significant to Dr. Waters because, as her report explains, the Menactra vaccine is T-lymphocyte mediated, which means that the immune system responds to the vaccine by generating T-lymphocytes to create immunity. *Id.* at 5-6. Robert's immune system was primed to deliver these cells due to his

⁷ Dr. Chang cited Robert's blood work (CBC) on the day of the vaccine, noting a normal white blood cell count of 7.6 K/uLs, which is indicative, to Dr. Chang of the lack of a viral infection.

first dose of Menactra several years earlier. From these two facts, Dr. Waters drew the conclusion that “the causation of lymphocytic myocarditis by the meningococcal vaccine [was] lymphocytes [that] gravitated to the heart’s conduction system causing a lethal arrhythmia and sudden death.” *Id.* at 6-7. She drew further support for this contention from two known cases of “myocarditis associated with meningococcal vaccine and hepatitis B vaccine.” *Id.* at 6. (citing the *Barton* study which will be discussed below). Dr. Waters testified at the entitlement hearing that 50% of myocarditis cases are not caused by viruses and that she believed Robert’s case was one that was not caused by viruses, but was instead caused by Robert’s immune system generating T-lymphocytes in response to the Menactra vaccine. Tr. at 87 (July 27, 2017).

Dr. Water’s report also mentions a virology screen done as part of the autopsy bloodwork. Her report states that it was negative for a viral infection. This was cited in the report’s conclusion section as support for the idea that the lymphocytic response was from the vaccine rather than a virus.⁸ Pet.’s Ex. 13 at 7.

Respondent’s experts, Dr. Yeager and Dr. Folkerth, offered a more unified approach, both agreeing that Robert’s immune response to a virus caused the myocarditis. In his initial report, Dr. Yeager began with Robert’s autopsy findings from the heart tissue. Dr. Yeager centered on the fact that lymphocytic inflammatory infiltrate with focal myocyte necrosis was present in Robert’s heart tissue biopsy, not eosinophils. Resp’t Ex. A at 2. His report went on to explain the autopsy results and describe the differences between lymphocytic and eosinophilic myocarditis: according to medical literature, lymphocytic myocarditis is generally associated with viral infections, and eosinophilic myocarditis, or hypersensitivity myocarditis, is sometimes associated with vaccines. *Id.* at 3 (citations omitted). In Dr. Yeager’s supplemental report, submitted in response to Drs. Chang and Waters, he emphatically stated that “the cause of the myocarditis was almost certainly viral, and the preceding meningococcal vaccination was entirely unrelated to the subsequent events.” Resp’t Ex. E at 3. The key fact is the lack of eosinophils in Robert’s heart tissue.

Dr. Yeager noted that, to date, only two cases are reported in the literature of myocarditis occurring after a meningococcal vaccination. Resp’t Ex. A at 3. One case occurred two days after three vaccines were

⁸ Dr. Water’s report also noted the lack of other indications of a recent viral infection in Robert’s medical history.

administration, one of which was a meningococcal conjugate, and the diagnosis was based on clinical, laboratory and imaging findings. *Id.* (citations omitted). In the second case of vaccine-caused myocarditis, a biopsy after the vaccine demonstrated eosinophilic infiltration with areas of eosinophilic degranulation along with immune complexes, complement and fibrin deposition.” *Id.* (citations omitted). His report further notes that the bulk of the known vaccine-induced myocarditis cases are after smallpox vaccines. *Id.* (citations omitted). Dr. Yeager concluded that eosinophilic infiltration would be required for a diagnosis of hypersensitivity or drug related myocarditis, which was not observed in Robert’s case. *Id.* at 4. In other words, eosinophilic myocarditis was incompatible with the evidence found in Robert’s heart tissue, but a diagnosis of lymphocytic myocarditis was consistent with Robert’s heart biopsy results.

In his supplemental report, Dr. Yeager also addressed Robert’s bloodwork on the day of the vaccine administration. He explained that, because Robert’s blood specimen was collected on the same day as the vaccination, the peripheral eosinophilia of 9.4% in Robert’s clinical record cannot be definitively ascribed to the Menactra vaccine. Resp’t Ex. E at 2. Dr. Yeager also notes that the high eosinophil levels in Robert’s blood may have been related to the anti-convulsant medications Robert was taking, since anti-seizure drugs are common causes of peripheral eosinophilia.⁹ *Id.*

Dr. Folkerth likewise concluded that Robert’s death was due to lymphocytic myocarditis, unrelated to the Menactra vaccine. Dr. Folkerth testified that she relied on the histology reflected in Robert’s autopsy. Tr at 96-97 (July 27, 2017). Dr. Folkerth stated that the pattern of inflammation in Robert’s heart and the lymphocytes that were present were evidence of viral myocarditis. *Id.* at 108-109. She also noted that the heart tissue showed inflammation in the epicardial fat, and in Dr. Folkerth’s opinion, that was an indicator of the severity of the inflammation in Robert’s heart. *Id.* at 139-140. In her report, Dr. Folkerth also noted that lymphocytic myocarditis is caused, in most cases, by a viral infection. Resp’t Ex. C at 5. In cases of viral myocarditis, Dr. Folkerth also explained that it is not uncommon for the patient to be asymptomatic, as Robert was before his death. Tr. at 12.

In Robert’s case, both petitioner’s and respondent’s experts agreed that Robert’s heart tissue extraction, or endomyocardial biopsy, conducted during the autopsy showed lymphocytic infiltrate. *Yates*, 2020 WL 2313691

⁹ Dr. Yeager also referenced an earlier January 2012 blood test in which Robert’s eosinophil level was reported to be 6%.

at *35. Endomyocardial biopsy, taking tissue samples of the heart, is considered the “gold standard” for diagnosing myocarditis, and determining the type of myocarditis. *Id.* at *35. Respondent’s experts also agreed that there was no histopathological evidence of eosinophilic infiltrate in Robert’s heart tissue, but instead showed lymphocytic infiltrate. *Id.*

Drs. Yeager, and Folkerth, as well as petitioner’s expert, Dr. Waters, agreed that the absence of eosinophils in the biopsy precluded a diagnosis of eosinophilic myocarditis. *Id.* In contrast, Dr. Chang opined that the absence of eosinophils in Robert’s myocardial tissue specimen did not preclude the diagnosis of “a relatively acute inflammatory process in the myocardium as a direct result of the vaccination.” Pet.’s Ex. 11 at 4.

Another point of contention for the parties’ experts centered on whether any testing had been completed to determine if Robert suffered from a virus at the time of death. One method of making that determination is through a viral panel assay. During the entitlement hearing, Dr. Folkerth admitted that she mistakenly believed that a virus panel assay test had been performed during Robert’s autopsy. *Yates*, 2020 WL 2313691 at *3. After confirmation from the examiner’s office by petitioner’s counsel, it was determined that none had been performed. *Id.* Dr. Waters, one of plaintiff’s experts, had used Dr. Folkerth’s report of that viral assay in writing her own report. *Id.* Petitioner moved to have Dr. Folkerth’s report and testimony barred, and respondent offered to have any reference to the assay excluded. *Id.* The Special Master sought to have the tests performed after the hearing. Unfortunately, Luminex testing was not possible because the tissue slides that would be required were destroyed six months after Robert’s death. *Id.* The Special Master thus advised the parties that the mistaken information would be ignored and that neither party would get the “benefit or detriment” of the absence of Luminex Virus Panel Assay testing. *Id.*

IV. The Special Master’s Decision

On April 16, 2020, the Special Master held that the petitioner failed to put forth a prima facie case of causation, and that the evidence submitted established that Robert’s cause of death was lymphocytic myocarditis which is “most commonly caused by viral infection,” i.e., not by the vaccination. *Id.* at *39-40. Because Robert’s heart tissue showed only lymphocytic infiltrate, the Special Master determined that Robert suffered from lymphocytic, not eosinophilic, myocarditis. *Id.* The Special Master found

petitioner's theory implausible because it did not adequately address Robert's cause of death, lymphocytic myocarditis

The Special Master found that petitioner failed to offer a reputable medical theory that the Menactra vaccine can cause lymphocytic myocarditis. *Id.* at *36. The Special Master based this conclusion on two factors. First, petitioner's expert, Dr. Waters could not explain how the Menactra vaccine could cause lymphocytic myocarditis, nor could Dr. Waters identify any literature that showed an association between vaccines and the lymphocytic myocarditis found during Robert's autopsy. *Id.* at *37. Second, neither Dr. Waters nor Dr. Chang explained how the Menactra vaccine caused a hypersensitivity reaction resulting in lymphocytic myocarditis and cardiac death. *Id.* Dr. Waters opined that the Menactra vaccine can cause an anamnestic T-lymphocyte cell response to Menactra, which in turn causes inflammation resulting in a hypersensitivity response. *Id.* Dr. Waters admitted, however, that hypersensitivity myocarditis is eosinophilic by definition. *Id.* Respondent's expert, Dr. Yeager, responded that Dr. Waters' theory that "the Menactra vaccine produced T-lymphocytes that gravitate to the cardiac conduction system causing lymphocytic myocarditis cannot be found anywhere in the available medical literature." *Id.* at *38. The Special Master agreed with Dr. Yeager.

Dr. Chang opined that hypersensitivity myocarditis could be characterized by either eosinophils or lymphocytes. *Id.* at *38. He testified that whether a patient had lymphocytic myocarditis or eosinophilic myocarditis was of no concern to him because his focus was on clinical symptoms and treating the patient. *Id.* Dr. Yeager again responded that this opinion was unsupported by the medical literature because a hypersensitivity reaction is indicated by the presence of eosinophils. *Id.* The Special Master agreed.

Although petitioner's experts opined that Robert suffered a hypersensitivity reaction to Menactra, regardless of Robert's specific diagnosis of lymphocytic myocarditis, the Special Master found this opinion unsupported. *Id.* at *38. Dr. Waters testified that "hypersensitivity myocarditis" is a clinical term and "lymphocytic myocarditis" is a histological term. *Id.* She continued: "a clinical diagnosis of hypersensitivity myocarditis could have a predominantly lymphocytic infiltrate." *Id.* She submitted that Robert had a Type IV delayed hypersensitivity reaction, stating that Type IV reactions have a wide range of symptoms. *Id.* The Special Master observed that Dr. Waters did not submit literature connecting

Type IV hypersensitivity reactions with lymphocytic myocarditis nor a Type IV hypersensitivity reaction. *Id.*

The Special Master also noted that neither Dr. Waters nor Dr. Chang revealed how Robert could be asymptomatic between July 27, 2012, and July 30, 2012, if in fact the vaccine caused Robert to have a hypersensitivity reaction, resulting in fulminant myocarditis after the Menactra vaccine. *Id.* at *39. Instead, the Special Master observed that petitioner recalled Robert behaving normally, playing video games, and attending school without issue in the days following Robert's Menactra vaccination. *Id.* Dr. Yeager asserted that the literature demonstrates that cases of viral myocarditis, presumably unlike hypersensitivity myocarditis, are commonly asymptomatic. *Id.*

Finally, the Special Master held that petitioner's experts had not explained why the three-day interval between Robert's vaccination and death was "an appropriate time frame" for a hypersensitivity reaction. *Id.* at *40. In contrast, respondent's expert stated that the inflammatory pattern on Robert's autopsy is not consistent with a hypersensitivity reaction, explaining that Robert's autopsy showed he had lymphocytes in the epicardial fat, the outside layer of the heart, which was an indicator that not only the heart, but the tissue around the heart, was affected. *Id.* The type of inflammation exhibited in Robert's autopsy report concerning his heart would take "days to weeks to develop." *Id.*

Based on the medical records, medical literature submitted by the parties, and testimony given, the Special Master determined that respondent's experts were more persuasive and their opinions more consistent with all the literature submitted. *Id.* at *38. We find no error in these conclusions, as discussed below.

DISCUSSION

This court has jurisdiction to review the Special Master's decision in accordance with 42 U.S.C. § 300aa-12. Our review is deferential, only setting aside decisions when they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" *Id.* § 300aa-12(e). When the Special Master has considered the relevant evidence and articulated a rational basis for the decision, reversible error is "extremely difficult to demonstrate." *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). We do "not reweigh the factual evidence,

assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder.” *Porter v. Sec’y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011).

A petitioner may seek compensation for “any illness, disability, injury, or condition” sustained or significantly aggravated by a vaccine. 42 U.S.C. §§ 300aa-11(c)(1) to 13(a)(1)(A). When a petitioner seeks compensation for an injury caused by an off-table injury, a vaccine other than those injuries listed on the Vaccine Injury Table, petitioner must prove causation in fact. *Althen*, 418 F.3d at 1278 (citing 42 U.S.C. § 300aa-13(a)(1)(A)). Petitioner must show that the vaccination caused the injury by proving three elements by a preponderance of the evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Id.*

A different showing corresponds to each of the elements, but the same evidence may be used to prove more than one element. *Id.* First, petitioner must provide a reputable medical theory that demonstrates that the vaccine can cause the alleged injury. *Id.* A petitioner is not, however, required to submit medical literature, propose a generally accepted theory, or demonstrate proof of scientific certainty. *See Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009). Yet, petitioner cannot prevail on “a ‘plausible’ or ‘possible’ causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence.” *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citing *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1332 (Fed. Cir. 2010)). “[A] mere showing of a proximate temporal relationship between vaccination and injury” is insufficient to prove actual causation. *Althen*, 418 F.3d at 1278.

To demonstrate a logical sequence of cause and effect, petitioner may use reputable medical or scientific evidence, including medical records. *See Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (citations omitted). Additionally, the treating physician’s opinion is entitled to weight, particularly because it was created contemporaneously. *Id.* Finally, petitioner must establish that there is a “medically-acceptable” timeframe between the vaccination and alleged injury that is consistent with

the theory of how the vaccine could cause the injury. *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

The central dispute in this case was whether the myocarditis that lead to Robert's heart failure was caused by a virus or a more generalized hypersensitivity reaction to the vaccine. It was petitioner's burden to prove the latter by preponderant evidence. Although petitioner failed to establish its causation theory and thus respondent had no duty to establish a cause unrelated to the vaccine, the Special Master was convinced by the government's position that a viral cause was more likely than not to blame for the deadly myocarditis. On review, petitioner makes several objections to the Special Master's findings, but her arguments revolve mostly around the evidence, or lack thereof, of a virus infecting Robert at the time of vaccination.¹⁰

Petitioner urges that the medical records from the day Robert was vaccinated conclusively establish that he did not have a viral infection on that day. Presumably, petitioner also believes that she has established that Robert did not have a virus on the day he died either. Petitioner points to the records from Dr. Barth's physical examination of Robert on July 27, 2012. In them, Dr. Barth reports that Robert was, other than recent seizure episodes, healthy. No cardiac issues or other symptoms associated with a viral infection were recorded. And, most important to petitioner's theory, the blood test done that day showed a normal white blood cell count. Those two facts—chiefly the latter—are relied on throughout petitioner's motion. Petitioner argues repeatedly that the lack of evidence of a virus on the day of vaccination is incompatible with a conclusion that a virus is to blame for Robert's death. The conclusion for Ms. Yates therefore is that the Special Master was arbitrary when she credited the opinions of respondent's experts, because those opinions were based primarily on an assumption that the medical

¹⁰ Petitioner also makes much of the Special Master's treatment of the lack of a viral assay. We find no abuse of discretion in the Special Master's decision that the lack of such a test would not be held against either party. That result could not have prejudiced petitioner, whose argument on review is based primarily on the lack of evidence of a virus. Further, the fact that no assay was performed did not call into question Dr. Folkerth's larger opinions in any way as Dr. Folkerth was operating under the assumption that the assay provided no evidence of a virus.

records do not support. The Special Master's conclusion therefore is not borne out by the evidence, according to petitioner.

The other piece of evidence that petitioner highlights in her motion for review is a one-page abstract of a study that Dr. Chang submitted after the hearing: A.P. Burke, et al., *Hypersensitivity Myocarditis*, 115 Arch. Pathol. Lab. Med. 764-69 (1991), which was marked as Pet.'s Ex. 24. Petitioner avers that the authors found that the degree of infiltrate in cardiac tissue was unrelated to the symptoms of hypersensitivity myocarditis. Pet.'s Mot. for Review 16. The authors of that study examined tissue samples from 69 cases of hypersensitivity myocarditis. Eosinophils were found in 30 of those samples and lymphocytes in 12 of them.¹¹ The conclusion for the authors was that "cardiac symptoms were not related to the degree of cellular infiltrate." *Id.* (citing Pet.'s Ex. 24). The Special Master recited the same findings in her decision but added one additional finding noted in the abstract: The authors defined hypersensitivity myocarditis "by the presence of eosinophils, a mixed lymphohistiocytic infiltrate along natural planes of separation, and an absence of fibrosis or granulation tissue in areas of infiltrate." 2020 WL 2313691 at *16 (citing Pet.'s Ex. 24). Also relevant from that abstract was the statement that "infiltrates may be missed by endomyocardial biopsy due to facility of lesions."¹² Pet.'s Ex. 24. From these brief statements, petitioner draws support for her experts' opinion that a reaction to a vaccine might also cause lymphocytes to be present in the

¹¹ We note that, at least as to the eosinophils, these findings appear to be from liver tissue samples, not cardiac tissue.

¹² Petitioner's motion also cites one of the studies submitted by Dr. Yeager regarding reactions to the smallpox vaccine: Dimitri C. Cassimatis et al., *Smallpox Vaccination and Myopericarditis: A Clinical Review*, 43 J. Am. Coll. Cardiol. 1503-10 (2004), marked as Resp't Ex. A-8 (attached to Dr. Yeager's report). Petitioner quotes a statement therein: "in more than half the cases, infiltrates may be missed by endomyocardial biopsy due to focality of lesions." We were unable to locate this statement in that study. We note, however, that this study, like the *Burke* study above, found a mixed infiltrate of lymphocytic infiltrate with eosinophil degranulation in areas of myocardial necrosis. "These findings support a non-infectious pathogenesis of inflammation, similar to hypersensitivity myocarditis." *Cassimatis* at 1509. Of note, however, is that even in such instances, the presence of eosinophils was noted.

cardiac tissue and that the posthumous biopsy might have inadvertently missed the presence of eosinophils.

Petitioner wraps up her motion by concluding that she proved that it was more likely than not that Robert “died from a type of myocarditis that was non-viral, i.e., an acute hypersensitivity reaction to the meningitis vaccines evidenced by lymphocytes in the heart tissue samples . . . and elevated levels of eosinophils in the peripheral blood evidencing the onset of an allergic reaction.” Pet.’s Mot. for Review 24. Petitioner urges that her experts had demonstrated “how the lymphocytes in Robert’s heart had been induced by an acute allergic hypersensitivity reaction to the [vaccine].” *Id.* We disagree.

I. The Finding That The Cause Of Death Was Lymphocytic Myocarditis Was Not Unreasonable

We find no error in the Special Master’s conclusion that Robert died from lymphocytic myocarditis. The medical examiner concluded the same. Three of the four experts agreed that the absence of eosinophils in Robert’s cardiac tissue generally precluded a diagnosis of eosinophilic myocarditis. Dr. Chang alone opined that a hypersensitive reaction to the vaccine might result in lymphocytic infiltration of the heart. Although the two studies, *Burke* and *Cassimatis*, cited on review, provide some evidence that a mixed infiltrate of eosinophils and lymphocytes has been noted in cases of eosinophilic myocarditis, that does not explain away the fact that Robert’s heart tissue showed only an infiltration of lymphocytes. Further, the *Burke* study’s finding that the symptoms of myocarditis did not correlate directly to the level of tissue infiltration does not provide support for either theory. We read that only as stating that the level of infiltration of, either or both, lymphocytes and eosinophils cannot be correlated directly to the severity of the myocarditis observed.¹³

In theory, the possibility exists that there were eosinophils present in Robert’s cardiac tissue that went unsampled by the medical examiner. That

¹³ We were hampered, as was the Special Master, by the fact that only the abstract of that study was submitted to the Special Master. The abstract does not provide the necessary context to read anything further into the statement that the level of infiltration observed did not correlate with the severity of the symptoms of hypersensitivity myocarditis suffered.

possibility, however, does not cast doubt on the Special Master's conclusion. She had only the evidence available and could not rely on the notional possibility of the existence of evidence unknown and now unknowable. The uncontroverted fact is that the biopsy revealed only lymphocytes. From that, respondent's experts inferred lymphocytic myocarditis. That result is supported by the literature presented. It was therefore entirely rational for the Special Master to conclude that such was the cause of death. It is certainly rational to credit that diagnosis over one that would require the presence of eosinophils, of which there is no evidence. The only remaining question is whether petitioner otherwise provided a reliable explanation of how the vaccine caused lymphocytic myocarditis. That leaves Dr. Water's alternative theory.

II. Petitioner Did Not Show How The Vaccine Caused An Infiltration Of Lymphocytes in Robert's Heart

We begin with the lack of evidence of a virus on the day that Robert was vaccinated. Contrary to petitioner's argument on review, that absence does not conclusively establish any fact. The absence of evidence of a thing is not evidence of its absence. The argument to the contrary is an appeal to ignorance, a logical fallacy. As the Special Master correctly held, it is unknown whether Robert was virus free at the time of his Menactra vaccination.¹⁴ *Yates*, 2020 WL 2313691 at *36. Based on the evidence from three days later, however, a different conclusion was reached.

Respondent's experts inferred a viral infection as the cause of death from the presence only of lymphocytes in Robert's heart tissue on the day he died. The Special Master found this inference reasonable and relied on it. Neither Dr. Chang nor Dr. Waters specifically opined that this was fallacious or otherwise an unreasonable conclusion. Instead, they drew contrary inferences from the lack of indication of a viral infection three days earlier. In other words, they assumed away the possibility of a virus, leaving only the vaccine as the likely casual factor. As between the two inferences, we find, like the Special Master, the former more reasonable as it is supported by

¹⁴ Petitioner also cites Robert's white blood cell count from the day of vaccination, which was within normal range. No expert was asked nor otherwise opined that this was conclusive evidence that Robert was uninfected by a virus. This is not to mention the possibility of an infection in the three days before he died. Additional evidence regarding the meaning of that blood cell count was not provided.

affirmative evidence. That leaves only Dr. Water's alternative theory that the vaccine caused the lymphocytic myocarditis.

Dr. Waters testified and wrote in her report that the vaccine could have caused lymphocytic myocarditis because the meningococcal vaccine causes the body to produce T-cells (a type of lymphocyte) to generate the immunity sought. That may be the case, but, as the Special Master stated, that does not explain how those cells caused myocarditis. There is also a total lack of evidence in the literature presented of such a causal connection. The *Barton* study cited by petitioner in her motion for review dealt with eosinophilic myocarditis and is therefore irrelevant to this theory.¹⁵ The *Thanjan* study did not involve a biopsy nor a determination of which type of myocarditis was suffered.¹⁶ The smallpox vaccine case studies submitted likewise showed only eosinophilic reactions. The Special Master was neither arbitrary nor capricious in not crediting this theory of causation.

CONCLUSION

The Special Master had a reasonable basis for her conclusions, and that is all that is required on review to this court under the Vaccine Act. The evidence pointed away from the causal theories presented by petitioner. Respondent provided preponderant evidence of a viral infection as the causal agent. We find no legal error in how the Special Master weighed the evidence nor in how she applied the *Althen* factors. Affirmance is thus appropriate.

Because the Special Master rationally determined that petitioner did not demonstrate causation of the injury sustained, and the Special Master did not otherwise act arbitrarily or in violation of law, we affirm her decision. Accordingly, we deny petitioner's motion for review. The clerk is directed to enter judgment accordingly.

¹⁵ Michelle Barton et al., *Eosinophilic Myocarditis Temporally Associated With Conjugate Meningococcal C and Hepatitis B Vaccines in Children*, 27 *Pediatr. Infect. Dis. J.* 831-35 (2008), marked as Pet.'s Ex. 17.

¹⁶ Maria T. Thanjan et al., *Acute Myopericarditis After Multiple Vaccinations in an Adolescent: Case Report and Review of the Literature*, 119 *Pediatrics* 1400-03 (2007), marked as Pet.'s Ex. 8 and Resp't Ex. A-11. It was also attached to Respondent's Exhibit C.

s/Eric G. Bruggink
ERIC G. BRUGGINK
Senior Judge